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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 08/049,147 | 04/19/93 | SINOFSKY | E B0410/7207 |

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33M1/1130

SHAY, D EXAMINER

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| ART UNIT | PAPER NUMBER |
| 3309 | II |

DATE MAILED: 11/30/94

This is a communication from the examiner in charge of your application
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on August 16, 1994 This action is made final.

A shortened statutory period for response to this action is set to expire — month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. Claims 44-59 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims 1-43 have been cancelled.

3. Claims _____ are allowed.

4. Claims 44-59 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable, not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been approved by the examiner. disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed on _____, has been approved. disapproved (see explanation).

12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other _____

EXAMINER'S ACTION

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The double patenting rejections, set forth in the previous office action are hereby withdrawn in view of the terminal disclaimer filed August 18, 1994. The rejection under 35 USC 112, first paragraph regarding the use of a liquid for flushing is hereby withdrawn in view of Applicants remarks.

The objection to the specification and rejection of claims 44-49 and 53-56 based on transmitting fluid to the surgical site is hereby repeated. The indefiniteness rejection of claims 47 and 48 is hereby repeated. The rejection under 35 USC 103 of claims 41-59 as unpatentable over Malyshev in view of L'Esperance ('541) is hereby repeated.

Applicant argues that because the step of irrigating the surgical site while ablating tissue was known, citing Hussein and Goldenberg, one of ordinary skill would understand that the recitation at page 15 of the originally filed disclosure of delivering fluid to the probe lens tip area was meant to teach that the fluid was delivered to the surgical site as well. The examiner cannot agree, and believes that one of ordinary skill would be under the impression that the flushing was intended to be restricted to the probe tip to prevent blood or other tissue from contaminating the optical surface of the probe tip. Similarly, the examiner would not make the leap that because endoscopic and artheroscopic laser procedures were known at the time of Applicants invention, then Applicants invention was

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intended to encompass these laser procedures as well, despite the fact that they are nowhere mentioned in the disclosure.

The rejection of claims 47 and 48 has been repeated because these claims only recite structure and not method steps. It has been well established in *Ex Parte Pfeiffer*, 782 OG 639, 1962 CD 408 that "to be entitled to weight.... structural limitations must affect the method in a manipulative sense and not amount to mere claiming of use of a particular structure."

Applicant argues, regarding the obviousness rejection, that there is no suggestion to combine L'Esperance ('541) and Malyshev and actually teaches away from the combination. The examiner must, respectfully, disagree. It is first noted that L'Esperance ('541) teaches both articulated arm (as used by Malyshev) and fiber optic delivery systems and L'Esperance ('541) further notes in the paragraph spanning columns 3 and 4 that the fiber optic system provides a greater flexibility of manipulation than articulated arms. It is unclear how Applicant can allege that there is no teaching to provide the substitution when such a suggestion is specifically set forth in the reference itself. Applicant then argues that since L'Esperance states that when a fiber is used some other laser such as an Argon laser should be used. It is noted that the suggestion is merely to use a laser other than a carbon dioxide laser. One having ordinary skill in the art, when substituting a fiber for the articulated arm of

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Malyshev have would, recognized that, in order to adhere to the ^{law} 11/29/94 method of Malyshev wavelengths would still be selected from the ranges taught thereby.

Applicant then argues that the combination does not cover the claimed invention because Malyshev teaches using only a portion of Applicant's claimed range. The examiner notes that since the claims encompass wavelengths taught by the prior art, they are rendered obvious thereby.

Applicant then argues that Applicant was the first to identify the claimed range as being one that combined the attributes of being highly absorbed by water, having absorption lengths that were about right for tissue removal, minimized scattering, and able to be transmitted down existing fiber optic cable. While this may be true, Holmium lasers were used for surgery long before Applicants effective filing date. It is well established law that "where the substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance" In re Graf 145 USPQ 197. It is also established that "the references may suggest doing what an applicant has done, even though workers in the art were ignorant of the existence of the problem." Thus this argument is not convincing. The Affidavit has been fully and carefully considered, but does not overcome the rejection as the surgical use of wavelengths in the

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claimed range was known prior to Applicants effective date.

Applicant then argues that since some wavelengths in the upper range of Malyshev were not transmittable through fiber optics at the time the invention was made. This may true, however, even assuming, arguendo that one of ordinary skill in he art would be unable to determine that fiber optics should only be used with the wavelength that can be transmitted through them, L'Esperance specifically teaches this .

Applicant then cites a long standing need for a system to remove tissue from deep within the body. The examiner must note that a variety of systems were disclosed prior to Applicants effective date. Restricting the list to only those patents submitted in the information disclosure statement: Takano; Bass et al; Loeb ('188 and '688); Hussein ('407); Goldman; Choy; Pinnow et al; and Davi all taught systems for providing tissue removal deep within the body before Applicants effective date. It is further noted that the systems of Pinnow et al and Davi employed carbon dioxide lasers to remove the tissue. Thus Applicants allegation of a long standing need is not persuasive.

Regarding Applicants renewed request for interference, the examiner notes that claim 7 of the '354 patent requires that the delivery end of the fiber positioned adjacent to the tissue to be ablated. This limitation cannot be supported by Applicants disclosure. Applicant then argues that the statement in the

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preamble of the Boutacuff claims is merely a statement of intended use and the recitation of an endoscopic or arthroscopic procedure does not render them separately patentable from applicants claims. The examiner must, respectfully disagree, as Applicants European Patent Office Document 214,712 published 3/87 which is part of the same family of applications as the instant application was part of the body of art considered prior to the issuance of the Notice of Allowability based on the endoscopic procedure. Since all the claims were deemed allowable over the disclosure, Applicants assertion that the instant claims are fully supported by the instant disclosure and define the same patentable invention as the claims to Boutacuff et al is not convincing.

Applicant's arguments filed August 16, 1994 have been fully considered but they are not deemed to be persuasive.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Serial No. 049,147

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Any inquiry concerning this communication should be directed
to David Shay at telephone number (703) 308-2215.

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November 15, 1994
November 22, 1994
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